

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

GLEND A JOHNSON and
STEVEN LUCIER,

Plaintiffs,

v.

SMITHKLINE BEECHAM CORP., *et al.*,

Defendants.

No. 2:11-cv-005782-PD

Electronically Filed

This Document Relates to:

DARREN GRIGGS, *et al.*,

Plaintiffs,

v.

GLAXOSMITHKLINE LLC, *et al.*,

Defendants.

ANSWER AND JURY DEMAND OF DEFENDANT SANOFI-AVENTIS U.S. LLC

Defendant Sanofi-Aventis U.S. LLC, by and through its undersigned counsel, hereby answers Plaintiffs' Complaint (the "Complaint").

INTRODUCTORY STATEMENT

The overwhelming majority of Plaintiffs' allegations concern events that occurred more than half a century ago. Sanofi-Aventis U.S. LLC is named in this case as the alleged successor to the William S. Merrell Company, National Drug Company, and Richardson-Merrell, Inc. (collectively, "Merrell"). The Merrell entities have not existed for many years. Due to the

passage of time and changes in ownership, no Merrell employees with any direct knowledge of the events alleged in the Complaint remain employees of Sanofi-Aventis U.S. LLC.

Accordingly, Sanofi-Aventis U.S. LLC is without knowledge or information concerning many of Plaintiffs' allegations and, on that basis, it denies those allegations as further specified below.

This case is at an early stage, and Sanofi-Aventis U.S. expressly reserves its rights to amend this Answer as appropriate.

As to each allegation, Sanofi-Aventis U.S. LLC responds as follows. All allegations are denied unless specifically admitted.

I. INTRODUCTION¹

1. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 1, and therefore denies the same.

2. Answering the allegations of Paragraph 2, Sanofi-Aventis U.S. LLC states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago, and that the limitations period has expired on Plaintiffs' claims herein. Sanofi-Aventis U.S. LLC further states that Merrell distributed thalidomide as part of a clinical trial. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 2, and therefore denies the same.

¹ Sanofi-Aventis U.S. LLC repeats Plaintiffs' section headings in order to assist the reader. To the extent the section headings set forth substantive allegations, Sanofi-Aventis U.S. LLC denies each and every one and by repeating them here makes no admission of any sort. They are included purely for the convenience of the reader.

3. Sanofi-Aventis U.S. LLC denies that it engaged in the acts described in Paragraph 3. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 3, and therefore denies the same.

4. Answering the allegations of Paragraph 4, Sanofi-Aventis U.S. LLC states that information about the link between thalidomide and birth defects in the United States has been publicly available for decades. Sanofi-Aventis U.S. LLC denies that it engaged in the acts described in Paragraph 4. Sanofi-Aventis U.S. LLC further denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 4, and therefore denies the same.

5. The allegations in Paragraph 5 are pejorative characterizations and not factual allegations, and accordingly no response is required. To the extent a response is required, Sanofi-Aventis U.S. LLC denies that it engaged in the acts described in Paragraph 5. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 5, and therefore denies the same.

6. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 6, and therefore denies the same.

7. To the extent Paragraph 7 alleges what Plaintiffs' mothers' knew, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 7.

8. To the extent Paragraph 8 alleges what Plaintiffs' mothers' knew, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations and

therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 8.

9. Sanofi-Aventis U.S. LLC denies that it engaged in the acts described in the first sentence of Paragraph 9. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 9, and therefore denies the same.

10. To the extent the allegations of Paragraph 10 are intended to summarize allegations set forth in Plaintiffs' Complaint, the allegations are improper and require no response. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC admits that Plaintiffs seek damages in this action but denies that Plaintiffs are entitled to any relief whatsoever. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 10.

11. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 11, and therefore denies the same.

12. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 12, and therefore denies the same.

13. To the extent the second sentence of Paragraph 13 alleges any wrongful act or omission by Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 13, and therefore denies the same.

14. To the extent the third sentence of Paragraph 14 alleges any wrongful act or omission by Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 14, and therefore denies the same.

15. Answering the allegations of Paragraph 15, Sanofi-Aventis U.S. LLC states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago. To the extent Paragraph 15 alleges facts concerning the nature of Plaintiffs' birth defects or what they knew about thalidomide and when, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 15.

II. THE PARTIES

A. Plaintiffs

1. Plaintiff Darren Griggs

16. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 16, and therefore denies the same.

17. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 17, and therefore denies the same.

18. To the extent the allegations of Paragraph 18 characterize claims and defenses in this case, the allegations are improper and require no response. To the extent the allegations of Paragraph 18 characterize publicly available medical or scientific information, such material speaks for itself. To the extent that the allegations of Paragraph 18 refer to Plaintiff's alleged injuries and their alleged cause, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 18, and therefore denies the same. Sanofi-Aventis U.S. LLC further states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 18.

2. Plaintiff Carolyn Jean Grover

19. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 19, and therefore denies the same.

20. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 20, and therefore denies the same.

21. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 21, and therefore denies the same.

3. Plaintiff William Tyler, III

22. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 22, and therefore denies the same.

23. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 23, and therefore denies the same.

24. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 24, and therefore denies the same.

B. Defendants

1. Defendant GlaxoSmithKline LLC

25. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 25, and therefore denies the same.

26. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 26, and therefore denies the same.

2. Defendant GlaxoSmithKline Holdings (Americas) Inc.

27. Answering the allegations of Paragraph 27, Sanofi-Aventis U.S. LLC denies that Defendant GlaxoSmithKline Holdings, Inc. (“GSK Holdings”) has a principal place of business in Pennsylvania. *See Johnson v. SmithKline Beecham Corp.*, 724 F.3d 337 (3d Cir. 2013). Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 27, and therefore denies the same.

3. Defendant Sanofi-Aventis, U.S., LLC

28. Answering the allegations of Paragraph 28, Sanofi-Aventis U.S. LLC states that it is a Delaware limited liability company that maintains its headquarters at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC further states that the Sanofi family of companies acquired certain successors of Merrell, and that Merrell entered into a licensing agreement with Grünenthal GmbH (“Grünenthal”) with respect to thalidomide in the United States and Canada. Sanofi-Aventis U.S. LLC further states that it is a healthcare company engaged in the research, development, and marketing of prescription drugs in the United States. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 28.

4. Defendant Grünenthal GmbH

29. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 29, and therefore denies the same.

I. JURISDICTION AND VENUE

30. The allegations in Paragraph 30 state a legal conclusion to which no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same.

31. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 31, and therefore denies the same.

32. To the extent the allegations in Paragraph 32 assert a legal conclusion regarding the propriety of jurisdiction over GlaxoSmithKline LLC (“GSK LLC”), no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 32, and therefore denies the same.

33. To the extent the allegations in Paragraph 33 assert a legal conclusion regarding the propriety of jurisdiction over GSK Holdings, no response is required. Answering the remaining allegations of Paragraph 33, Sanofi-Aventis U.S. LLC denies that GSK Holdings has a principal place of business in Pennsylvania. *See Johnson v. SmithKline Beecham Corp.*, 724 F.3d 337 (3d Cir. 2013). Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 33, and therefore denies the same.

34. To the extent the allegations in Paragraph 34 assert a legal conclusion regarding the propriety of jurisdiction over Sanofi-Aventis U.S. LLC, no response is required. Answering the remaining allegations of Paragraph 34, Sanofi-Aventis U.S. LLC states that the Sanofi family of companies acquired certain successors of Merrell, and that Merrell entered into a licensing agreement with Grünenthal with respect to thalidomide in the United States and Canada. Sanofi-Aventis U.S. LLC further states that it is a healthcare company engaged in the research, development, and marketing of prescription drugs in the United States, and that it has employees

and a research and development facility in Malvern, Pennsylvania. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 34.

35. To the extent the allegations in Paragraph 35 assert a legal conclusion regarding the propriety of jurisdiction over Grünenthal GmbH, no response is required. Answering the remaining allegations of Paragraph 35, Sanofi-Aventis U.S. LLC states that Merrell entered into a licensing agreement with Grünenthal with respect to thalidomide in the United States and Canada. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 35, and therefore denies the same.

36. To the extent the allegations in Paragraph 36 assert legal conclusions regarding the propriety of venue as to Defendants, no response is required. Answering the remaining allegations of Paragraph 36, Sanofi-Aventis U.S. LLC denies that GSK Holdings has a principal place of business in Pennsylvania. *See Johnson v. SmithKline Beecham Corp.*, 724 F.3d 337 (3d Cir. 2013). Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 36, and therefore denies the same.

II. STATEMENT OF FACTS

A. Grünenthal and Thalidomide

37. To the extent the allegations of Paragraph 37 are intended to summarize allegations set forth in Plaintiffs' Complaint, the allegations are improper and require no response. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 37, and therefore denies the same.

38. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 38, and therefore denies the same.

39. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 39, and therefore denies the same.

40. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 40, and therefore denies the same.

41. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 41, and therefore denies the same.

42. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 42, and therefore denies the same.

43. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 43, and therefore denies the same.

44. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 44, and therefore denies the same.

45. Answering the allegations of Paragraph 45, Sanofi-Aventis U.S. LLC states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 45, and therefore denies the same.

B. “Clinical Trials” in the United States

46. Answering the allegations of Paragraph 46, Sanofi-Aventis U.S. LLC states that Grünenthal and Vick Chemical Company, the predecessor of Richardson-Merrell, Inc., entered a preliminary licensing agreement relating to thalidomide in October 1958. Sanofi-Aventis U.S. LLC states that the William S. Merrell Company submitted an NDA to market thalidomide under the trade name “Kevadon” in September 1960, and National Drug Company submitted an NDA

to market thalidomide under the trade name “Contergan” in November 1960. Sanofi-Aventis U.S. LLC further states that J.T. Baker was a subsidiary of Richardson-Merrell, Inc. and was at one time a manufacturer of the raw drug substance called thalidomide. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 46, and therefore denies the same.

47. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 47, and therefore denies the same.

48. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 48, and therefore denies the same.

49. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 49, and therefore denies the same.

50. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 50, and therefore denies the same.

51. Answering the allegations of Paragraph 51, Sanofi-Aventis U.S. LLC states that the William S. Merrell Company submitted an NDA to market thalidomide in September 1960. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 51, and therefore denies the same.

52. Answering the allegations of Paragraph 52, Sanofi-Aventis U.S. LLC states that Merrell distributed thalidomide as part of a clinical trial. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 52, and therefore denies the same.

53. Answering the allegations of Paragraph 53, Sanofi-Aventis U.S. LLC states that publicly available sources from the 1960s reported that Merrell distributed approximately 2.5

million thalidomide tablets to 1,267 physicians. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 53, and therefore denies the same.

54. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 54, and therefore denies the same.

55. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 55, and therefore denies the same.

56. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 56, and therefore denies the same.

57. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 57, and therefore denies the same.

58. Answering the allegations of Paragraph 58, Sanofi-Aventis U.S. LLC states that Merrell withdrew its NDAs for thalidomide in March 1962, and that Merrell thereafter notified physicians of the possible dangers from thalidomide. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 58, and therefore denies the same.

59. Answering the allegations of Paragraph 59, Sanofi-Aventis U.S. LLC states that the link between thalidomide and birth defects has been widely known for decades and that the limitations period has expired on Plaintiffs' claims herein. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 59, and therefore denies the same.

60. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 60, and therefore denies the same.

C. Thalidomide Injuries

61. The allegations of Paragraph 61 are improper characterizations and not factual allegations, and accordingly no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 61.

62. The allegations in Paragraph 62 are pejorative characterizations and not factual allegations, and accordingly no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 62, and therefore denies the same.

63. The allegations in Paragraph 63 are pejorative characterizations and not factual allegations, and accordingly no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 63, and therefore denies the same.

64. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 64, and therefore denies the same.

65. Answering the allegations of Paragraph 65, Sanofi-Aventis U.S. LLC states that the link between thalidomide and birth defects has been widely known for decades and that the limitations period has expired on Plaintiffs' claims herein. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 65, and therefore denies the same.

66. The allegations in Paragraph 66 are pejorative characterizations and not factual allegations, and accordingly no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 66, and therefore denies the same.

D. Defendants fraudulently convinced Congress and the public that thalidomide could not have caused injuries in the United States, falsely claiming that it was almost entirely unavailable in the United States and failing to disclose that testing on pregnant women here had resulted in the births of at least two malformed babies by 1958.

67. Answering the allegations of Paragraph 67, Sanofi-Aventis U.S. LLC states that information about the clinical trials of thalidomide in the United States has been publicly available for decades. Sanofi-Aventis U.S. LLC further states that the articles and sources cited speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 67, and therefore denies the same.

68. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi U.S. LLC further denies that it has made any false statements about thalidomide usage in the United States. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 68, and therefore denies the same.

69. Sanofi-Aventis U.S. LLC denies that it engaged in the acts described in the first sentence of Paragraph 69. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 69, and therefore denies the same.

70. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 70, and therefore denies the same.

71. Answering the allegations of Paragraph 71, Sanofi-Aventis U.S. LLC states that information about the clinical trial of thalidomide in the United States by Merrell has been publicly available for decades. Sanofi-Aventis U.S. LLC further states that Dr. Carl A. Bunde, former director of medical research for the William S. Merrell Company, made statements and gave testimony regarding thalidomide, and those statements and testimony speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 71, and therefore denies the same.

72. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 72, and therefore denies the same.

73. Answering the allegations of Paragraph 73, Sanofi-Aventis U.S. LLC states that Dr. Bunde made statements regarding thalidomide, and those statements speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 73, and therefore denies the same

E. Defendants successfully and fraudulently convinced Congress and the public that they did nothing illegal in developing thalidomide and distributing it in the United States.

74. Answering the allegations of Paragraph 74, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC denies that it engaged in the acts described in Paragraph 74. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 74, and therefore denies the same.

75. Answering the allegations of Paragraph 75, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC

lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 75, and therefore denies the same.

76. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 76, and therefore denies the same.

77. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 77, and therefore denies the same.

78. Answering the allegations of Paragraph 78, Sanofi-Aventis U.S. LLC states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago. Sanofi-Aventis U.S. LLC admits that there was no Freedom of Information Act in the United States prior to 1966 and admits that there was no Internet in the 1950s and 1960s. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 78, and therefore denies the same.

79. Answering the allegations of Paragraph 79, Sanofi-Aventis U.S. LLC states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 79, and therefore denies the same.

80. Answering the allegations of Paragraph 80, Sanofi-Aventis U.S. LLC states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 80, and therefore denies the same.

F. Smith, Kline & French's 50-Year Secret: By 1958, at Least One of Its Study Subjects Had Given Birth To A Malformed Baby.

81. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 81, and therefore denies the same.

82. To the extent the letters and documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 82, and therefore denies the same.

83. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 83, and therefore denies the same.

84. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 84, and therefore denies the same.

85. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 85, and therefore denies the same.

86. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the letter to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 86, and therefore denies the same.

87. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 87, and therefore denies the same.

88. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 88, and therefore denies the same.

89. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 89, and therefore denies the same.

90. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 90, and therefore denies the same.

91. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 91, and therefore denies the same.

92. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 92, and therefore denies the same.

93. Answering the allegations of Paragraph 93, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 93.

94. Answering the allegations of Paragraph 94, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 94.

95. Answering the allegations of Paragraph 95, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 95.

96. Answering the allegations of Paragraph 96, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for

themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 96.

97. Answering the allegations of Paragraph 97, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 97.

98. Answering the allegations of Paragraph 98, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 98.

99. Answering the allegations of Paragraph 99, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 99.

100. Answering the allegations of Paragraph 100, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 100.

101. Answering the allegations of Paragraph 101, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 101.

102. Answering the allegations of Paragraph 102, Sanofi-Aventis U.S. LLC states that the 1938 Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC otherwise denies the allegations in Paragraph 102.

103. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 103, and therefore denies the same.

104. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 104, and therefore denies the same.

105. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 105, and therefore denies the same.

106. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 106, and therefore denies the same.

107. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 107, and therefore denies the same.

108. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 108, and therefore denies the same.

109. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 109, and therefore denies the same.

110. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 110, and therefore denies the same.

111. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 111, and therefore denies the same.

112. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 112, and therefore denies the same.

113. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the memoranda to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 113, and therefore denies the same.

114. To the extent the memorandum to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 114, and therefore denies the same.

115. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 115, and therefore denies the same.

116. To the extent the letter to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 116, and therefore denies the same.

117. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 117, and therefore denies the same.

118. Answering the allegations of Paragraph 118, Sanofi-Aventis U.S. LLC states that FDA regulations speak for themselves and any attempt to characterize them is denied. To the extent Paragraph 118 asserts a legal conclusion concerning GSK's legal duty, no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 118, and therefore denies the same.

119. Answering the allegations of Paragraph 119, Sanofi-Aventis U.S. LLC states that FDA regulations speak for themselves and any attempt to characterize them is denied. To the extent Paragraph 119 asserts a legal conclusion concerning GSK's legal duty, no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 119, and therefore denies the same.

120. Answering the allegations of Paragraph 120, Sanofi-Aventis U.S. LLC states that NDA regulations speak for themselves and any attempt to characterize them is denied. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 120, and therefore denies the same.

121. To the extent Paragraph 121 asserts a legal conclusion concerning GSK's legal duty, no response is required. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 121, and therefore denies the same.

122. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 122, and therefore denies the same.

123. To the extent the statement to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 123, and therefore denies the same.

124. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 124, and therefore denies the same.

125. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 125, and therefore denies the same.

126. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 126, and therefore denies the same.

G. Richardson-Merrell was the North American face of thalidomide and Grünenthal's partner in concealment.

127. Answering the allegations of Paragraph 127, Sanofi-Aventis U.S. LLC states that Grünenthal and Vick Chemical Company, the predecessor of Richardson-Merrell, Inc., entered a preliminary licensing agreement relating to thalidomide in October 1958, and that agreement speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 127, and therefore denies the same.

128. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 128, and therefore denies the same.

129. Answering the allegations of Paragraph 129, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide, and any other documents, to the extent they exist, speak for themselves. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 129, and therefore denies the same.

130. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 130, and therefore denies the same.

131. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 131, and therefore denies the same.

132. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 132, and therefore denies the same.

H. Merrell experiments on pregnant women.

133. Answering the allegations of Paragraph 133, Sanofi-Aventis U.S. LLC states that Merrell distributed thalidomide as part of a clinical trial. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 133, and therefore denies the same.

134. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 134, and therefore denies the same.

135. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 135, and therefore denies the same.

136. Answering the allegations of Paragraph 136, Sanofi-Aventis U.S. LLC states that the "Kevadon Hospital Clinical Program" script speaks for itself. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 136, and therefore denies the same.

137. Answering the allegations of Paragraph 137, Sanofi-Aventis U.S. LLC states that the William S. Merrell Company submitted an NDA to market thalidomide under the trade name

“Kevadon” in September 1960, and National Drug Company submitted an NDA to market thalidomide under the trade name “Contergan” in November 1960. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs’ action timely. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 137, and therefore denies the same.

138. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs’ action timely. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 138, and therefore denies the same.

139. Answering the allegations of Paragraph 139, Sanofi-Aventis U.S. LLC states that the licensing agreement between Merrell and Grünenthal speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 139, and therefore denies the same.

140. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs’ action timely. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 140, and therefore denies the same.

141. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 141, and therefore denies the same.

142. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 142, and therefore denies the same.

143. Answering the allegations of Paragraph 143, Sanofi-Aventis U.S. LLC states that the “Kevadon Hospital Clinical Program” manual speaks for itself. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs’ action timely. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 143, and therefore denies the same.

144. Answering the allegations of Paragraph 144, Sanofi-Aventis U.S. LLC states that the “Kevadon Hospital Clinical Program” manual speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 144, and therefore denies the same.

145. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 145, and therefore denies the same.

146. Answering the allegations of Paragraph 146, Sanofi-Aventis U.S. LLC states that Merrell distributed thalidomide as part of a clinical trial. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 146, and therefore denies the same.

147. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs’ action timely. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 147, and therefore denies the same.

148. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 148, and therefore denies the same.

149. Answering the allegations of Paragraph 149, Sanofi-Aventis U.S. LLC states that publicly available information from the 1960s reported that Merrell distributed approximately 2.5 million thalidomide tablets to 1,267 physicians. Sanofi-Aventis U.S. LLC further states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 149, and therefore denies the same.

150. Answering the allegations of Paragraph 150, Sanofi-Aventis U.S. LLC states that information about the clinical trial of thalidomide in the United States by Merrell has been publicly available for decades. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 150, and therefore denies the same.

151. To the extent Paragraph 151 asserts a legal conclusion concerning Merrell's duty of disclosure, no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 151, and therefore denies the same.

152. Answering the allegations of Paragraph 152, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 152, and therefore denies the same.

153. To the extent the letters to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 153, and therefore denies the same.

154. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 154, and therefore denies the same.

155. Answering the allegations of Paragraph 155, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 155, and therefore denies the same.

156. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 156, and therefore denies the same.

157. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 157, and therefore denies the same.

158. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 158, and therefore denies the same.

159. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 159, and therefore denies the same.

160. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 160, and therefore denies the same.

161. To the extent the study and articles to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 161, and therefore denies the same.

162. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 162, and therefore denies the same.

163. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 163, and therefore denies the same.

164. Answering the allegations of Paragraph 164, Sanofi-Aventis U.S. LLC states that Dr. Raymond Nulsen, a clinical trial investigator, published the results of a thalidomide study in the June 1961 issue of *American Journal of Obstetrics and Gynecology*, and this article speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 164, and therefore denies the same.

165. To the extent the publications to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 165, and therefore denies the same.

166. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 166, and therefore denies the same.

167. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 167, and therefore denies the same.

168. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 168, and therefore denies the same.

169. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 169, and therefore denies the same.

170. Answering the allegations of Paragraph 170, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 170, and therefore denies the same.

171. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 171, and therefore denies the same.

172. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 172, and therefore denies the same.

173. Answering the allegations of Paragraph 173, Sanofi-Aventis U.S. LLC states that Frank Getman, then president of the William S. Merrell Company, sent a letter regarding thalidomide to physicians on August 10, 1962, and this letter speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 173, and therefore denies the same.

174. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 174, and therefore denies the same.

175. To the extent the material to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 175, and therefore denies the same.

176. To the extent the article to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 176, and therefore denies the same.

177. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 177, and therefore denies the same.

178. To the extent the letters and remarks to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 178, and therefore denies the same.

179. To the extent the letter to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 179, and therefore denies the same.

180. To the extent the letter to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 180, and therefore denies the same.

181. Answering the allegations of Paragraph 181, Sanofi-Aventis U.S. LLC states that Merrell withdrew its NDAs for thalidomide in March 1962. Sanofi-Aventis U.S. LLC further states that Merrell sent letters regarding thalidomide to clinical investigators in March 1962, and these letters speak for themselves. To the extent the allegations in Paragraph 181 consist of speculation about the conduct of physicians, such allegations are improper and are denied on that basis. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 181, and therefore denies the same.

182. Answering the allegations of Paragraph 182, Sanofi-Aventis U.S. LLC states that the March 1962 letters speak for themselves. To the extent the allegations in Paragraph 182

consist of speculation about the conduct of physicians, such allegations are improper and are denied on that basis. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 182, and therefore denies the same.

183. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 183, and therefore denies the same.

184. Answering the allegations of Paragraph 184, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 184, and therefore denies the same.

185. Answering the allegations of Paragraph 185, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 185, and therefore denies the same.

186. Answering the allegations of Paragraph 186, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 186, and therefore denies the same.

187. Answering the allegations of Paragraph 187, Sanofi-Aventis U.S. LLC states that Frank Getman, then president of the William S. Merrell Company, sent a letter regarding thalidomide to physicians on August 10, 1962, and this letter speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 187, and therefore denies the same.

188. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 188, and therefore denies the same.

189. Answering the allegations of Paragraph 189, Sanofi-Aventis U.S. LLC states that publicly available information from the 1960s reported that Merrell distributed approximately 2.5 million thalidomide tablets to 1,267 physicians. Sanofi-Aventis U.S. LLC further states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 189, and therefore denies the same.

190. To the extent the writing to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 190, and therefore denies the same.

191. Answering the allegations of Paragraph 191, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 191, and therefore denies the same.

192. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 192, and therefore denies the same.

193. Answering the allegations of Paragraph 193, Sanofi-Aventis U.S. LLC states that the "Kevadon Hospital Clinical Program" manual and any brochures, to the extent they exist, speak for themselves. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 193, and therefore denies the same.

194. Answering the allegations of Paragraph 194, Sanofi-Aventis U.S. LLC states that Dr. Bunde's statements regarding thalidomide speak for themselves. Sanofi-Aventis U.S. LLC

lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 194, and therefore denies the same.

195. Answering the allegations of Paragraph 195, Sanofi-Aventis U.S. LLC states that Frank Getman, then president of the William S. Merrell Company, sent a letter regarding thalidomide to physicians on August 10, 1962, and this letter speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 195, and therefore denies the same.

196. Answering the allegations of Paragraph 196, Sanofi-Aventis U.S. LLC states that the August 1962 letter speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 196, and therefore denies the same.

197. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 197, and therefore denies the same.

198. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 198, and therefore denies the same.

199. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 199, and therefore denies the same.

200. Answering the allegations of Paragraph 200, Sanofi-Aventis U.S. LLC states that the licensing agreement between Merrell and Grünenthal and the other documents cited, to the extent they exist, speak for themselves. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 200, and therefore denies the same.

201. To the extent the statements to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 201, and therefore denies the same.

I. Drug developer and manufacturer Grünenthal, a Nazi-lead company whose motto was to “succeed at any cost,” knew that thalidomide could cause birth defects by 1956 but never revealed that risk.

202. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs’ action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 202, and therefore denies the same.

203. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs’ action timely. To the extent the interview to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 203, and therefore denies the same.

204. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 204, and therefore denies the same.

205. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs’ action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 205, and therefore denies the same.

206. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 206, and therefore denies the same.

207. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 207, and therefore denies the same.

208. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 208, and therefore denies the same.

209. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 209, and therefore denies the same.

210. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 210, and therefore denies the same.

211. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 211, and therefore denies the same.

212. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 212, and therefore denies the same.

213. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 213, and therefore denies the same.

214. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 214, and therefore denies the same.

215. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 215, and therefore denies the same.

216. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 216, and therefore denies the same.

217. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or

information sufficient to form a belief as to the allegations in Paragraph 217, and therefore denies the same.

218. To the extent the article to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 218, and therefore denies the same.

219. To the extent the patent applications to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 219, and therefore denies the same.

220. To the extent the report to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 220, and therefore denies the same.

221. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 221, and therefore denies the same.

222. To the extent the brochure to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 222, and therefore denies the same.

223. To the extent the paper to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 223, and therefore denies the same.

224. To the extent the letters and paper to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 224, and therefore denies the same.

225. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the brochure and other documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 225, and therefore denies the same.

226. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 226, and therefore denies the same.

227. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 227, and therefore denies the same.

228. To the extent the advertisements to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 228, and therefore denies the same.

229. To the extent the memorandum to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 229, and therefore denies the same.

230. To the extent the advertisements, sales policy documents, and letter to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 230, and therefore denies the same.

231. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 231, and therefore denies the same.

232. To the extent the studies to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 232, and therefore denies the same.

233. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 233, and therefore denies the same.

234. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 234, and therefore denies the same.

235. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 235, and therefore denies the same.

236. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 236, and therefore denies the same.

237. To the extent the letter and other documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 237, and therefore denies the same.

238. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 238, and therefore denies the same.

239. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 239, and therefore denies the same.

240. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 240, and therefore denies the same.

241. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 241, and therefore denies the same.

242. To the extent the letter to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 242, and therefore denies the same.

243. To the extent the letter, recommendation, and advertisement to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 243, and therefore denies the same.

244. To the extent the brochures to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 244, and therefore denies the same.

245. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 245, and therefore denies the same.

246. To the extent the brochure to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 246, and therefore denies the same.

247. To the extent the publication and brochure to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 247, and therefore denies the same.

248. To the extent the directive to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 248, and therefore denies the same.

249. To the extent the letter to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 249, and therefore denies the same.

250. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 250, and therefore denies the same.

251. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 251, and therefore denies the same.

252. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 252, and therefore denies the same.

253. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 253, and therefore denies the same.

254. To the extent the label and letters to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 254, and therefore denies the same.

255. To the extent the letter to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 255, and therefore denies the same.

256. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 256, and therefore denies the same.

257. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 257, and therefore denies the same.

258. To the extent the report to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 258, and therefore denies the same.

259. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 259, and therefore denies the same.

260. To the extent the letter and paper to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 260, and therefore denies the same.

261. To the extent the paper to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 261, and therefore denies the same.

262. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 262, and therefore denies the same.

263. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 263, and therefore denies the same.

264. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 264, and therefore denies the same.

265. To the extent the article and report to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 265, and therefore denies the same.

266. To the extent the article to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 266, and therefore denies the same.

267. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 267, and therefore denies the same.

268. To the extent the studies, telegram, and letter to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 268, and therefore denies the same.

269. To the extent the study and articles to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 269, and therefore denies the same.

270. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 270, and therefore denies the same.

271. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 271, and therefore denies the same.

272. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 272, and therefore denies the same.

273. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 273, and therefore denies the same.

274. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 274, and therefore denies the same.

275. To the extent the letter to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 275, and therefore denies the same.

276. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the documents to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 276, and therefore denies the same.

277. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 277, and therefore denies the same.

278. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the indictment and memorandum to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 278, and therefore denies the same.

279. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 279, and therefore denies the same.

280. To the extent the compilation, package labels, packaging, promotional materials, and circular to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S.

LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 280, and therefore denies the same.

281. To the extent the meeting minutes to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 281, and therefore denies the same.

282. To the extent the records and advertisement to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 282, and therefore denies the same.

283. To the extent the product packaging and labeling to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 283, and therefore denies the same.

284. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 284, and therefore denies the same.

285. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 285, and therefore denies the same.

286. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 286, and therefore denies the same.

287. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 287, and therefore denies the same.

288. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 288, and therefore denies the same.

289. To the extent the advertisement to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 289, and therefore denies the same.

290. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 290, and therefore denies the same.

291. To the extent the circulars to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 291, and therefore denies the same.

292. To the extent the letter to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 292, and therefore denies the same.

293. To the extent the newspaper story to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 293, and therefore denies the same.

294. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 294, and therefore denies the same.

295. To the extent the article to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 295, and therefore denies the same.

296. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 296, and therefore denies the same.

297. To the extent the advertisement to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 297, and therefore denies the same.

298. To the extent the statement to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 298, and therefore denies the same.

299. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 299, and therefore denies the same.

300. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 300, and therefore denies the same.

301. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 301, and therefore denies the same.

302. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 302, and therefore denies the same.

303. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 303, and therefore denies the same.

304. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 304, and therefore denies the same.

305. To the extent the document to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 305, and therefore denies the same.

306. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the website to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 306, and therefore denies the same.

307. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. To the extent the website and judgment to which this Paragraph refers exist, they speak for themselves. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 307, and therefore denies the same.

308. Sanofi-Aventis U.S. LLC denies that any alleged recently obtained evidence renders Plaintiffs' action timely. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 308, and therefore denies the same.

309. To the extent the article to which this Paragraph refers exists, it speaks for itself. Sanofi-Aventis U.S. LLC otherwise lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 309, and therefore denies the same.

III. CAUSES OF ACTION

FIRST CAUSE OF ACTION

NEGLIGENCE AND NEGLIGENT DESIGN (All Defendants)

310. Answering the allegations of Paragraph 310, Sanofi-Aventis U.S. LLC repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

311. To the extent the allegations of Paragraph 311 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 311.

312. To the extent the allegations of Paragraph 312 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 312.

313. To the extent the allegations of Paragraph 313 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 313.

314. To the extent the allegations of Paragraph 314 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 314.

315. To the extent the allegations of Paragraph 315 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 315.

316. To the extent the allegations of Paragraph 316 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 316.

317. To the extent the allegations of Paragraph 317 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 317.

318. To the extent the allegations in Paragraph 318 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 318.

319. To the extent the allegations in Paragraph 319 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 319.

320. To the extent the allegations in Paragraph 320 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information

sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 320.

321. To the extent the allegations in Paragraph 321 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 321.

322. To the extent the allegations in Paragraph 322 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 322.

323. To the extent the allegations in Paragraph 323 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 323.

324. To the extent the allegations in Paragraph 324 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 324.

325. To the extent the allegations in Paragraph 325 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 325.

326. To the extent the allegations in Paragraph 326 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 326.

327. To the extent the allegations in Paragraph 327 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 327.

328. To the extent the allegations in Paragraph 328 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 328.

329. To the extent the allegations in Paragraph 329, including all subparts thereof, are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. To the extent the allegations of Paragraph 329, including all subparts thereof, attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 329, including all subparts thereof.

330. To the extent the allegations in Paragraph 330 attempt to assert a legal conclusion, no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same.

331. To the extent the allegations in Paragraph 331 purport to assert a legal conclusion about direct and proximate results, no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same.

332. To the extent the allegations in Paragraph 332 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 332.

SECOND CAUSE OF ACTION

FRAUD AND NEGLIGENT MISREPRESENTATION (Grünenthal And Sanofi-Aventis)

333. Answering the allegations of Paragraph 333, Sanofi-Aventis U.S. LLC repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

334. To the extent this Paragraph relies on allegations in the Statement of Facts, Sanofi-Aventis U.S. LLC incorporates by reference its responses to each of the allegations of the Statement of Facts, as if set forth in full here. Sanofi-Aventis U.S. LLC denies that it engaged in the acts described in the first and second sentences of Paragraph 334. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 334, and therefore denies the same.

335. To the extent this Paragraph, including all subparts thereof, relies on allegations previously recited, Sanofi-Aventis U.S. LLC incorporates by reference its responses to each of the allegations above, as if set forth in full here. Answering the remaining allegations of Paragraph 335, Sanofi-Aventis U.S. LLC responds as follows:

- 1) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 1. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 1, and therefore denies the same.
- 2) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 2. To the extent the website to which this Subpart refers exist, it speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 2, and therefore denies the same.
- 3) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 3. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 3, and therefore denies the same.
- 4) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 4. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 4, and therefore denies the same.
- 5) Answering the allegations of Subpart 5, Sanofi-Aventis U.S. LLC states that publicly available information from the 1960s reported that Merrell distributed approximately 2.5 million thalidomide tablets as part of a clinical trial. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 5, and therefore denies the same.

- 6) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 6. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 6, and therefore denies the same.
- 7) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 7. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 7, and therefore denies the same.
- 8) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 8. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 8, and therefore denies the same.
- 9) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 9. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 9, and therefore denies the same.
- 10) Answering the allegations of Subpart 10, Sanofi-Aventis U.S. LLC states that Merrell distributed thalidomide as part of a clinical trial. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 10, and therefore denies the same.
- 11) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 11. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient

to form a belief as to the remaining allegations in Subpart 11, and therefore denies the same.

12) Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Subpart 12, and therefore denies the same.

13) Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Subpart 13, and therefore denies the same.

14) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 14. Sanofi-Aventis U.S. LLC states that J.T. Baker was a subsidiary of Richardson-Merrell, Inc. and was at one time a manufacturer of the raw drug substance called thalidomide. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 14, and therefore denies the same.

15) Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Subpart 15, and therefore denies the same.

16) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 16. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 16, and therefore denies the same.

17) Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Subpart 17, and therefore denies the same.

18) Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Subpart 18, and therefore denies the same.

19) Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Subpart 19, and therefore denies the same.

20) Sanofi-Aventis U.S. LLC denies that it engaged in any of the acts described in Subpart 20. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Subpart 20, and therefore denies the same.

336. To the extent Paragraph 336 asserts a legal conclusion concerning Defendants' duty of disclosure, no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 336, and therefore denies the same.

337. Answering the allegations of Paragraph 337, Sanofi-Aventis U.S. LLC states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago. To the extent the allegations in Paragraph 337 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 337.

338. Answering the allegations of Paragraph 338, Sanofi-Aventis U.S. LLC states that discovery of the link between thalidomide and birth defects was widely publicized throughout the world and the United States decades ago. Sanofi-Aventis U.S. LLC further states that information about the clinical trials of thalidomide in the United States has been publicly available for decades. To the extent the article and statements to which this Paragraph refers exist, they speak for themselves. To the extent the allegations in the first sentence of Paragraph

338 are directed toward Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 338, and therefore denies the same.

339. Answering the allegations of Paragraph 339, Sanofi-Aventis U.S. LLC states that information about the clinical trials of thalidomide in the United States has been publicly available for decades. To the extent the allegations in the first sentence of Paragraph 339 are directed toward Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 339, and therefore denies the same.

340. To the extent the allegations in Paragraph 340 purport to assert a legal conclusion about direct and proximate results, no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same.

341. To the extent the allegations in Paragraph 341 attempt to assert a legal conclusion about Plaintiffs' pleadings and the standards governing such pleadings, no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 341, and therefore denies the same.

THIRD CAUSE OF ACTION

FRAUD AND NEGLIGENT MISREPRESENTATION (Against GSK Defendants)

342. Answering the allegations of Paragraph 342, Sanofi-Aventis U.S. LLC repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

343. Answering the allegations of Paragraph 343, including all subparts thereof, Sanofi-Aventis U.S. LLC states that the documents cited speak for themselves. To the extent this Paragraph, including all subparts thereof, relies on allegations in the Statement of Facts, Sanofi-Aventis U.S. LLC incorporates by reference its responses to each of the allegations of the Statement of Facts, as if set forth in full here. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 343, including all subparts thereof, and therefore denies the same.

344. To the extent Paragraph 344 asserts a legal conclusion concerning GSK's duty of disclosure, no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 344, and therefore denies the same.

345. To the extent Paragraph 345 asserts a legal conclusion concerning GSK's duty of disclosure, no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 345, and therefore denies the same.

346. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 346, and therefore denies the same.

347. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 347, and therefore denies the same.

348. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 348, and therefore denies the same.

349. To the extent Paragraph 349 asserts a legal conclusion concerning GSK's duty of disclosure, no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information

sufficient to form a belief as to the remaining allegations in Paragraph 349, and therefore denies the same.

350. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 350, and therefore denies the same.

351. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 351, and therefore denies the same.

352. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 352, and therefore denies the same.

353. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 353, and therefore denies the same.

354. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 354, and therefore denies the same.

355. To the extent Paragraph 355 asserts a legal conclusion concerning GSK's duty of disclosure, no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 355, and therefore denies the same.

356. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 356, and therefore denies the same.

357. To the extent the allegations in Paragraph 357 purport to assert a legal conclusion about direct and proximate results, no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same.

358. To the extent the allegations in Paragraph 358 attempt to assert a legal conclusion about Plaintiffs' pleadings and the standards governing such pleadings, no response is required.

To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same.

Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 358, and therefore denies the same.

FOURTH CAUSE OF ACTION

NEGLIGENT HIRING (Against Grünenthal)

359. Answering the allegations of Paragraph 359, Sanofi-Aventis U.S. LLC repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

360. To the extent the allegations of Paragraph 360 attempt to set forth a legal duty, the allegations call for a legal conclusion to which no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 360, and therefore denies the same.

361. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 361, and therefore denies the same.

362. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 362, and therefore denies the same.

363. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 363, including all subparts thereof, and therefore denies the same.

364. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 364, and therefore denies the same.

365. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 365, and therefore denies the same.

FIFTH CAUSE OF ACTION

CONCERT OF ACTION (All Defendants)

366. Answering the allegations of Paragraph 366, Sanofi-Aventis U.S. LLC repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

367. To the extent the allegations in Paragraph 367 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 367.

368. To the extent the allegations in Paragraph 368 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 368.

369. To the extent the allegations in Paragraph 369 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 369.

370. Sanofi-Aventis U.S. LLC denies that it engaged in the acts described in the first sentence of Paragraph 370. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 370, and therefore denies the same.

371. To the extent the allegations in Paragraph 371 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information

sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 371.

372. To the extent the allegations in Paragraph 372 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 372.

373. To the extent the allegations in Paragraph 373 purport to assert a legal conclusion about direct and proximate results, no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same.

SIXTH CAUSE OF ACTION

CIVIL CONSPIRACY (All Defendants)

374. Answering the allegations of Paragraph 374, Sanofi-Aventis U.S. LLC repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

375. To the extent the allegations in Paragraph 375 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 375.

376. To the extent the allegations in Paragraph 376 attempt to assert a legal conclusion, no response is required. To the extent the allegations in Paragraph 376 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 376.

377. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 377, and therefore denies the same.

378. To the extent that the agreement referenced in this Paragraph exists, it speaks for itself. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 378, and therefore denies the same.

379. To the extent the allegations in Paragraph 379 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 379.

380. To the extent the allegations in Paragraph 380 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 380.

381. Sanofi-Aventis U.S. LLC denies that it engaged in the acts described in Paragraph 381. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 381, and therefore denies the same.

382. To the extent the allegations in Paragraph 382 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 382.

383. To the extent the allegations in Paragraph 383 attempt to assert legal conclusions, no response is required. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 383, and therefore denies the same.

384. To the extent the allegations in Paragraph 384 purport to assert a legal conclusion about direct and proximate results, no response is required. To the extent a response is deemed necessary, Sanofi-Aventis U.S. LLC denies the same.

VI. PUNITIVE DAMAGES

385. Answering the allegations of Paragraph 385, Sanofi-Aventis U.S. LLC repeats and incorporates by reference its response to all preceding paragraphs of this Answer as if fully set forth herein.

386. To the extent the allegations in the first sentence of Paragraph 386 are directed toward Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 386, and therefore denies the same.

387. To the extent the allegations in Paragraph 387 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 387.

388. To the extent the allegations in Paragraph 388 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 388.

389. To the extent the allegations in Paragraph 389 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 389.

390. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 390, and therefore denies the same.

391. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 391, and therefore denies the same.

392. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 392, and therefore denies the same.

393. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations in Paragraph 393, and therefore denies the same.

394. To the extent the allegations in the first and second sentences of Paragraph 394 are directed toward Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC denies the same. Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 394, and therefore denies the same.

395. To the extent the allegations in Paragraph 395 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 395.

396. To the extent the allegations in Paragraph 396 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 396.

397. To the extent the allegations in Paragraph 397 are directed toward Defendants other than Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S. LLC lacks knowledge or information

sufficient to form a belief as to the allegations, and therefore denies the same. Sanofi-Aventis U.S. LLC denies the remaining allegations in Paragraph 397.

PRAYER FOR RELIEF

Answering the paragraphs under the section titled “Prayer for Relief,” Sanofi-Aventis U.S. LLC admits that Plaintiffs seek the relief requested but denies that Plaintiffs are entitled to any relief whatsoever in this lawsuit.

AFFIRMATIVE DEFENSES²

FIRST AFFIRMATIVE DEFENSE

Plaintiffs’ Complaint fails to state a claim against Sanofi-Aventis U.S. LLC upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The Court lacks personal jurisdiction over Sanofi-Aventis U.S. LLC.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs’ claims should be dismissed due to improper venue and/or pursuant to the doctrine of *forum non conveniens*.

FOURTH AFFIRMATIVE DEFENSE

The claims set forth in Plaintiffs’ Complaint are barred in whole or in part by the applicable statutes of limitation and/or statutes of repose.

² Sanofi-Aventis U.S. LLC asserts the following affirmative defenses without admitting or conceding that all of the affirmative defenses listed below are affirmative defenses for which it carries the burden of proof.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the doctrine of laches.

SIXTH AFFIRMATIVE DEFENSE

Sanofi-Aventis U.S. LLC pleads collateral estoppel, res judicata, waiver, and failure to mitigate or minimize damages, if any.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are improperly joined because they did not arise out of the same transaction, occurrence, or series of transactions or occurrences.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred to the extent that Plaintiffs have released, settled, or otherwise compromised their claims.

NINTH AFFIRMATIVE DEFENSE

The alleged negligent or culpable conduct of Sanofi-Aventis U.S. LLC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiffs' alleged injuries.

TENTH AFFIRMATIVE DEFENSE

If Plaintiffs were injured and damaged, which injuries and damages are denied, such injuries and damages were the result of intervening or superseding events, factors, occurrences, or conditions, which were in no way caused by Sanofi-Aventis U.S. LLC and for which Sanofi-Aventis U.S. LLC is not responsible and not liable.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not suffered any actual loss or damage as a result of any actions of Sanofi-Aventis U.S. LLC or any conspiracy as alleged in the Complaint.

TWELFTH AFFIRMATIVE DEFENSE

Any verdict or judgment rendered against Sanofi-Aventis U.S. LLC must be reduced by those amounts that have or will, with reasonable certainty, replace, or indemnify Plaintiffs, in whole or in part, for any past or future claimed economic loss, from any collateral source such as insurance, Social Security, worker's compensation, or employee benefit programs.

THIRTEENTH AFFIRMATIVE DEFENSE

No act or omission of Sanofi-Aventis U.S. LLC was malicious, willful, wanton, reckless, grossly negligent, or intentional, and therefore any award of punitive damages is barred.

FOURTEENTH AFFIRMATIVE DEFENSE

To the extent that the requested relief seeks punitive damages, such damages would constitute forfeiture and an excessive fine on Sanofi-Aventis U.S. LLC in violation of the Eighth Amendment of the U.S. Constitution.

FIFTEENTH AFFIRMATIVE DEFENSE

The requested relief would deprive Sanofi-Aventis U.S. LLC of due process of law and the equal protection of laws as guaranteed by the Fourteenth Amendment of the U.S. Constitution.

SIXTEENTH AFFIRMATIVE DEFENSE

If acts, omissions or fault of other persons or entities for whom Sanofi-Aventis U.S. LLC has no liability caused Plaintiffs' alleged damages, then such acts, omissions or fault bar or limit

any recovery from Sanofi-Aventis U.S. LLC, as provided by Pennsylvania law or other applicable law.

SEVENTEENTH AFFIRMATIVE DEFENSE

When Merrell performed the conduct for which Sanofi-Aventis U.S. LLC is alleged to be liable in this case, Merrell lacked adequate notice that it could be liable over fifty years later to strangers with whom Merrell had no legal relationship. At the time Merrell engaged in the alleged conduct, no legal duty of the sort proposed in this case had been recognized. As such, the federal and state due process clauses preclude the imposition of liability on Sanofi-Aventis U.S. LLC, as do other constitutional limitations.

EIGHTEENTH AFFIRMATIVE DEFENSE

Sanofi-Aventis U.S. LLC hereby gives notice that it intends to rely upon any other defense that may become available or appear during the discovery proceedings in the case and hereby reserves the right to amend this Answer to assert any such defense. Sanofi-Aventis U.S. LLC also reserves the right to assert other and related defenses as may become available upon a determination of the law applicable to the action or any part thereof or claim therein.

NINETEENTH AFFIRMATIVE DEFENSE

Sanofi-Aventis U.S. LLC adopts by reference any other affirmative defense raised by other Defendants.

TWENTIETH AFFIRMATIVE DEFENSE

Sanofi-Aventis U.S. LLC relies upon all defenses contained in any applicable state statute or law.

WHEREFORE, Sanofi-Aventis U.S. LLC, having fully answered Plaintiffs' Complaint, prays that Plaintiffs take nothing by this suit and demands as follows:

1. That Plaintiffs' Complaint be dismissed with prejudice on the merits;
2. That Sanofi-Aventis U.S. LLC recover its costs and disbursements herein expended to the extent permitted under applicable law;
3. That Sanofi-Aventis U.S. LLC be granted leave to file an amended pleading upon conclusion of reasonable discovery, if necessary; and
4. That Sanofi-Aventis U.S. LLC be accorded all other relief to which it now or hereafter appears to be entitled.

JURY DEMAND

Sanofi-Aventis U.S. LLC hereby demands a jury trial on all issues so triable.

Dated: June 23, 2014

Respectfully submitted,

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Sanofi-Aventis U.S. LLC

CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2014, the foregoing document was filed electronically and is available for viewing and downloading from the CM/ECF system. I also certify that a true and correct copy of the foregoing document is being served this day on all counsel of record via transmission of Notices of Electronic Filing generated by CM/ECF.

/s/ Daniel S. Pariser

Daniel S. Pariser